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AUG 20 1998

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In Re: Patent Term Extension
Application for
U.S. Patent No. 4,572,912

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,572,912, which claims the human drug products PRELAY™ and REZULIN™ (troglitazone), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,534 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,534 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of September 3, 1997 (62 Fed. Reg. 46501). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,703) + 182 \\ &= 1,534 \text{ days}\end{aligned}$$

Since the regulatory review period began March 9, 1989, after the patent issue date (February 25, 1986), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the five year limitation of 35 U.S.C. § 156(g)(6)(A) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,572,912
Granted	:	February 25, 1986
Original Expiration Date ¹ :	:	August 28, 2004
Applicant	:	Takao Yoshioka et al.

¹Subject to the provisions of 35 U.S.C. § 41(b).

Owner of Record	:	Sankyo Company Limited
Title	:	Thiaxolidine Derivatives, Their Preparation and Compositions Containing Them
Classification	:	514/369
Product Trade Names	:	PRELAY™ and REZULIN™ (troglitazone)
Term Extended	:	1,534 days
Expiration Date of Extension	:	November 9, 2008

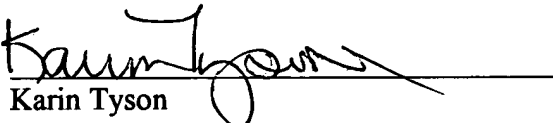
Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.


Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: PRELAY™ and REZULIN™
(troglitazone)
FDA Docket No.: 97E-0145